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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/652,938 09/02/2003 Manfred Watzele RDID03056US 2575 EXAMINER 23690 12/07/2005 7590 **Roche Diagnostics Corporation** MENON, KRISHNAN S 9115 Hague Road ART UNIT PAPER NUMBER PO Box 50457 Indianapolis, IN 46250-0457 1723

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)	[
Office Action Summary		10/652,938	WATZELE ET AL.	
		Examiner	Art Unit	
		Krishnan S. Menon	1723	
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the d	correspondence address	
WHIC - Exte after - If NO - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS OF THE MAILING THE MAIL	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from 1, cause the application to become ABANDONE	N. nely filed the mailing date of this communic D (35 U.S.C. § 133).	·
Status				
1)⊠	Responsive to communication(s) filed on 15 M	arch 2004.		
2a)[	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.			
3)[	Since this application is in condition for allowar			ts is
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.	
Disposit	ion of Claims			
5)□ 6)⊠	Claim(s) 1-12 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 1-12 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.		
Applicati	ion Papers			
10)⊠	The specification is objected to by the Examine The drawing(s) filed on <u>02 September 2003</u> is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction to oath or declaration is objected to by the Ex	are: a)⊠ accepted or b)⊡ object drawing(s) be held in abeyance. Section is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.12	` '
Priority ι	ınder 35 U.S.C. § 119		·	
12)⊠ a)[	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority application from the International Bureau  See the attached detailed Office action for a list of	s have been received. s have been received in Applicati ity documents have been receive I (PCT Rule 17.2(a)).	on No ed in this National Stage	
Attachment	t(s) e of References Cited (PTO-892)	4) 🔲 Interview Summary	(PTO 412)	
2) 🔲 Notice 3) 🔯 Inform	e of References Cited (P10-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) ' No(s)/Mail Date	Paper No(s)/Mail Da		

### **DETAILED ACTION**

Claims 1-12 are pending after the preliminary amendment of 1/26/04

#### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not identify the citizenship of each inventor.

#### Information Disclosure Statement

The NPL document "Harvard Apparatus Internet Site" was not considered because an internet site is subject to constant changes, and, cannot be considered as a dated publication. Accordingly, this reference was stricken out from the IDS.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-3 and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Manns (US 5,047,215).

Claim 1: Manns teaches a multi-well tray (figures 8-10; abstract) having plurality of chambers (28) in side-by side arrangement, with circumferential walls, membrane

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(22: see column 4 lines 29-35), the membrane is fixed at the periphery of each well by clamping between the front face (37) of the chamber wall and fixing parts (50,52), with grooves (38, 60) and ridges (44,58). See also figure 5-7. The 'microdialyser' in preamble has no particular patentable weight other than being the intended use; the multi-well plate of the reference is capable of such use. With respect to the "semipermeable membrane", given the broadest reasonable interpretation of the claim, the reference teaches a semipermeable membrane (cellulose acetate, etc — column 4 lines 29-35). 'Diffusion exchange between the sample chamber and the ... dialysate chamber ("dialysate chamber" is intended use) ... only possible through this membrane' is functional language, which the reference device is capable of; the molecular weight cut-of of the membrane is not positively recited.

Claim 2: membrane area is less than 50 mm2 – see column 1 lines 15-20 giving the diameter of the well at 0.66 cm, which has an area of about 32 mm2.

Claim 3: at least a part of the sample chambers are in liquid exchange contact with a dialysate chamber ("dialysate chamber" is intended use): all the wells in the reference can be in liquid exchange contact with the chamber (46), as seen in figure 1. 'At least pat of' would include all sample chambers. The chamber 46 is not in liquid contact with any other different set of sample chambers.

Claim 6: common dialysate chamber – 46.

Claim 7: common fixing part – see figure 10.

Claim 8: cellulose acetate membrane – column 4 lines 29-35.

Claim 9-11: 96-array – see figure 1.

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Claim 12: 9 mm center – center – column 1 line 20.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO
   00/44877 (US equivalent in English: Schels et al, US 6,670,173; herein after,

   Schels) in view of Manns (US 5,047,215).

Schels teaches a microdialysis device having a sample chamber (12) and dialysate chamber 10 separated by membrane 7; the periphery of the membrane 7 is fixed in compression between the groove on the circumferential ring part of the chamber 10 and the ridge on the bottom face of the sample chamber wall (see figure 5; and also figures 2-4). Sample chamber is open only to dialysate chamber 10 via the membrane 7 – having a individual dialysate chambers for the sample chamber. The membrane is cellulose acetate (column 4 line 63).

The teaching of the reference differs from the instant claims in the plurality of sample chambers, common dialysate chamber, dimensions such as wall thickness, membrane area, spacing of the sample chambers and the number of sample chambers in the device. All these are taught by the Manns reference as shown in paragraph 1 above. It would be obvious to one of ordinary skill in the art at the time of invention to

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use the teaching of Manns in the teaching of Schels for having a multiwell device for simultaneously handing multiple samples as taught by Manns (column 1 lines 10-20) for bioreactions as taught by Schels. Such multiwell plates are also well known in the art as taught by Manns.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon Patent Examiner December 2, 2005